ALERT

News from the UFMCC
on AIDS Legislation, Education, Research and Treatment.

FEBRUARY, 1991
EDITOR: Rev. Dr. Stephen Pieters

UFMCC HIV/AIDS CONFERENCE A SUCCESS!

Participants in the 1991 UFMCC HIV/AIDS Conference, "Empowering Response in the Rainbow Epidemic" were uniformly enthusiastic in their evaluations. Held outside Disney World at the Radisson Inn Maingate, and cosponsored by the UFMCC AIDS Ministry and the UFMCC Department of People of Color, the conference focused on issues related to people of color and HIV/AIDS, and was described as "extremely relevant to the UFMCC journey."

The conference began with a program which included the Rev. Elder Troy D. Perry speaking on "The State of AIDS in UFMCC Today," and a panel of persons with HIV/AIDS sharing their own experiences. Mr. Jesse Brown, a member of Morning Star MCC in Worcester, MA, movingly shared his confident response to his HIV diagnosis. An African-American heterosexual man and a Hispanic heterosexual man, both from Orlando, shared their struggles with AIDS. A white woman shared the story of how her husband and she have become foster parents to six HIV+ babies, all under the age of two. They have adopted three of the children.

During the medical update, Dr. Larry Siegel, of Key West, FL, shared his expertise about the drug and alcohol connection to HIV/AIDS. He also shared HIV/AIDS survival facts and statistics, encouraging us to continue to give hope in our ministries.

A powerful healing service, led by Rev. Elder Jeri Ann Harvey, concluded the first day of the conference. Rev. Elder Harvey spoke about "the absurdity of God," and powerfully "recharged the batteries" of many people involved in AIDS ministry.

The second day, the conference began to confront the issues of racism head-on, with meetings of the Department of People of Color, and White People Healing Racism. Rev. La Paula Turner, Executive Director of the Department of People of Color, and Rev. Steve Pieters led intense discussions that began in the morning, and continued in the afternoon plenary session led by Phillip Matthews and Scott Howard.

Mr. Matthews, the Minority Outreach Coordinator for the Northern Texas AIDS Interfaith Network, challenged white people to really listen to people of color. In analyzing the title of the conference, he powerfully focused the problem of gay white men and women bringing our decade's experience with AIDS into the African-American community without carefully examining our own racism and agendas. He encouraged white people to have "colossal ears and thick skins."

Some white people reflected that these discussions were the first time they had experienced a conversation about racism where they didn't feel "beat up or guilty," but grew in their understanding of the issues, for themselves personally, for UFMCC, and for society.

Saturday night, Sallie Perryman, Special Assistant to the Director of Policy for the AIDS Institute of the State of New York, preached a powerful sermon, and touched everyone with her interpretation of scripture, and the story of her husband's recovery from drugs and his death from AIDS. Perhaps one of the most powerful points of her sermon was when she explained that in spite of racial, economic, or sexual differences, we who are HIV+ are related by blood. We are family.

Sunday morning, Rev. Robert Pierce, Pastor of Church of the Trinity MCC in Sarasota, FL, wrote and led a beautiful communion service, and preached movingly from his own experience of living through aids. Rev. Pierce contributed a great deal to the conference, not only with his gift for liturgy, but with his presentation at the Saturday luncheon about his life and his journey with AIDS.

Rev. Sandi Robinson, Dean of Samaritan College, Phillip Matthews, and Sallie Perryman ended the conference with challenges from their hearts. God truly blessed this conference: one of the things that made this conference so special was the particular constellation of people who attended. Many people were touched by the way the Rev. Elder Troy Perry fully participated in the workshops, plenaries, and meetings, sharing intimately from his own experiences and feelings. As a direct result, many people felt freer to share from their hearts, and the conference became a real bonding and healing experience.

It is obvious that there is a great deal of work to do in confronting the racism in our churches, our Fellowship, and in the AIDS movement. This conference was a solid step in that direction, while also providing people in AIDS ministry the needed opportunity to network and hold each other and nurture each other through the continuing challenges of our work.

Women and AIDS Conference Report

(by Laura Thomas; from AIDS Treatment News, #118, 1/4/91; (415) 255-0588)

The first National Conference on Women and HIV Infection was held December 13-14, 1990, in Washington, DC. It marked the first time that so many women with HIV, care providers, and activists had met specifically to talk about women and AIDS. The main issues discussed at the conference were the need for adequate health care for women with HIV infection, the lack of knowledge about the progression of disease in women, the problems of women and clinical trials, and the difficulties of doing education and prevention for women. This is a preliminary report of some of the information from the conference.

Some of the most interesting statistics presented proved conclusively what we already knew: health care makes a difference. Pat Kloser, M.D., from the Newark Women's AIDS Clinic, showed that the women who were cared for in her clinic averaged 70.4 weeks between AIDS diagnosis and death, as compared to the women who went through the emergency room and hospital system there, who averaged only 27.5 weeks.

The clearest recommendation for care was that women with symptomatic HIV disease should get cervical and anal Pap smears every six months, followed up by colposcopies if necessary. Pap smears are recommended for all women once a year, and men with HIV may be interested in having anal Pap smears done, as well. A Pap smear is a test for unusual, possibly pre-cancerous cells. Women with suppressed immune systems are especially vulnerable to infection with HPV, (human papilloma virus) which causes cervical and other anogenital cancers. While there are not yet any truly effective treatments for cervical cancer or HPV infection in people with HIV, early detection and treatment offers the best hope of keeping it under control. Pap smears should become part of every woman's health care regimen, and we have heard that they are now going to be included in the standard of care for participants in AIDS Clinical Trials Group clinical trials.

There seems to be some evidence that the antimicrobial action of the PCP prophylaxis TMP-SMX (Bactrim or Septra) is causing vaginal candidiasis, or yeast infections, in women. It is well known that antibiotics such as penicillin can cause such infections, which many women have self-treated with acidophilus or yogurt, although we have not heard of any women on Septra taking acidophilus to counter the candidiasis. Vaginal candidiasis is also very common in women with HIV, so it may be hard to tell whether it is caused by Septra or not. TMP-SMX may also be prevening some of the HIV-related bacterial pneumonias that many women and injection drug users are getting.

Conflicting data was presented on the interaction of methadone and AZT. One clinician stated that methadone lowered levels of AZT in the blood, and another said that it nearly double AZT levels. Many recovering injection drug users are on methadone, so this will be an important drug interaction to study. As a group, injection drug users in clinical trials showed the same compliance rates as gay men did, debunking the myth of IDUs as irresponsible people. In fact, the most important predictor of compliance in a Boston trial of AZT was the belief in the efficacy of AZT, not the participant's drug using status or transmission route.

One woman with AIDS described her frustration at being unable to find a doctor who was willing to operate on her cervical cancer. Doctors discussed their difficulties in getting and keeping good nurses. Many women talked about the need for substance abuse treatment, and made it clear that they could not take care of their HIV infection without taking care of their substance abuse, and vice versa. We were encouraged to hear of community-based clinics for women with HIV; but speakers noted that women enter the health care system everywhere, and there are few obstretics and gynecology physicians, or emergency room personnel, who are trained to care for women with HIV.

ddC/ddI Approval Update

(by John S. James; from AIDS Treatment News, #118, 1/4/91; (415) 255-0588)

Much AIDS news today concerns the campaign for a rapid FDA evaluation of the experimental AIDS antivirals ddC and ddI - the issue we listed as the most important treatment development to watch in 1991 (AIDS Treatment News #117, 12/21,90). The decisions now being made will affect not only these drugs, but all critically important AIDS antivirals in the future; they will determine whether any future AIDS treatment, no matter how well it may work, could possibly travel the development and regulatory pipeline without many months or years of medically unnecessary delay. We are now seeing the beginnings of major changes; but at the same time there is widespread confusion, and sometimes chaotic miscommunication.

The meaning of the current controversies cannot be understood without background on the situation which now exists, and how it developed.

BACKGROUND: THE PROBLEM

Neither ddC or ddI are new; both could have been developed and approved at about the same time as AZT. ddC was delayed because of early toxicity; it was not known until later that the right dose was about 200 times less than the dose of AZT or ddI. As for ddI, it was well into human trials two years ago - and the subject of a loud and sometimes bitter public dispute between Ellen Cooper,

M.D., chief of the FDA's Division of Antiviral Drug Products, and Samuel Broder, M.D., director of the U.S. National Cancer Institute; the occasion was the first hearing of the Lasagna Committee, which issued its report on approval of new drugs for cancer and AIDS on Aug. 15, 1990. The dispute, an advance echo of what is happening today, concerned the FDA's refusal to approve the NCI's plan to begin testing ddI as a treatment for children with AIDS under two years old; the U.S. National Cancer Institute was ready to start this ddI trial two years ago but apparently the FDA wanted tests on adults to be finished before the tests with children began.

Two years later, one activist spoke of the spreading "ripple of terror that the trials [running now for ddI and ddC] are not what should have been designed." It seems that nobody thought through how the information to be generated by these trials - scheduled to run for about 18 months more - would be used to support drug approval. One effect of this lack of planning is that AZT, the first AIDS antiviral to reach FDA approval, shut the door behind it, keeping all rivals out. This happened despite the clear need for new therapies - shown most compellingly by epidemiological data suggesting that AZT has extended average survival after AIDS diagnosis by no more than several months. (This survival data includes patients not receiving AZT because of drug intolerance or other reasons; the benefit of AZT for those who do use it might be greater).

Much of the reason for the current complexity, confusion, and miscommunication stirred up by the push for early evaluation of ddC and ddI is the need to retrofit to cover for mistakes of the past. These mistakes occured because of lack of higher-level oversight and planning in the AIDS research process. Key positions have long been vacant, or filled with people unwilling to deal effectively with AIDS.

One of the problems in the current development of ddC and ddI is the lack of definition of what the trials are trying to prove. Normally, the goal would be to prove efficacy (i.e., that the drug works better than no treatment) for some group of patients. It should not be necessary to prove that the new drug is better than standard therapy - or even equal to it, because many patients cannot use the standard therapy, and because combination treatment using both the new and standard treatment is highly promising.

But since it would be unethical to run a placebo trial, ddC and ddI are being compared to AZT instead. Statistical efforts were made to use the old AZT-vs-placebo trial of four years ago to allow ddC and ddI to be mathematically compared with a placebo, even though no real placebo is being used in the current trial. This desperate attempt to forge a case for approval out of ill designed trials seems to have led to some of the recent controversy.

If the new drugs must be compared to AZT, then the next question is whether they must be proved superior, or only equivalent, to merit FDA approval. Equivalence, of course, would be the standard preferred. But there are statistical complications in proving equivalence. For example, in a trial to test whether one drug is better than another, the incentives are for researchers to run a tight, clean study, so that if there is a difference, it will be found. But in a test for equivalence, the incentives are for researchers to run a sloppy trial, because failure to find a difference means success. For this and other reasons, there is confusion now over whether proof of equivalence will be enough for approval of ddC or ddI, or whether proof of superiority will be required.

There are other problems with the current ddC and ddI trials, and with the regulatory process. One concern is that companies do not usually submit their data to the FDA until their NDA (New Drug Application) is finished; the FDA prefers to get the data all together, in order to save staff time. But an NDA is a large document, typically consisting of many volumes of paperwork. Anyone familiar with the influence of corporate and organizational cultures would expect that any time one organization generates such a document and passes it to another for evaluation, many points of disagreement or friction will almost certainly be found. Without inside knowledge of the operations at the FDA, we cannot know whether this potential problem does or does not in fact cause serious, avoidable delays. (If it does, procedures could be changed to encourage earlier collaboration for NDA review of critically important drugs).

Two years ago, NCI's Dr. Samuel Broder saw that no new AIDS antiviral would be approved unless procedures were changed. "If we have to compare every drug to AZT, with death as the endpoint of a trial, we're going to be in a situation where it will be very difficult to get any other antiretroviral approved for AIDS. It took us two years to get AZT out - how long do you think the next one will take? Five years, ten years? That's unacceptable!" (Quoted in Newsday, February 14, 1989; the comments were addressed to Dr. Ellen Cooper of the FDA. The context of the discussion was ddI. Dr. Cooper replied with the question, "Why don't you want to see a year's research in clinical trials on an antiretroviral before approval?")

Two years later, the trials of ddC and ddI still have months or years to run - and as we pointed out above they are not well focused on the important questions. This is the context of the growing movement to ask the FDA to call in the existing data now, look at all that is known about these drugs, and approve them if there is "substantial evidence" that they work.

WHEN I MET GOD

(by Woodie White, Concord, CA)

On August 13, 1986 at 7:10 pm, I heard, "You have AIDS. I'm sorry, you have AIDS." That's heard ringing in my ears. I was only 24 years old.

I grew up Catholic, Mormon, and Southern Baptist. I was taught that God didn't love me because of...., the list seemed like it went on and on. I got involved with drugs and alcohol and left the church and God. I gave God a good reason now to not love me.

I finally got off drugs and alcohol when I was 20 years old. I was Agnostic. I first heard of God again in the meetings of AA and NA. Boy, that was scary. I learned to believe in a higher power during this time. I couldn't bring myself to call that higher Power, "God".

Well, August 13 came and went, just like any other day. But, my life stopped. I lost my job, car, dog, relationship, part of my family, and once again - God. I had heard that AIDS was God's judgement on bad people. Christians said it, I believed it. I attempted suicide. No reason to live. I couldn't go on this way.

My good friend, Vicki, took me to an AIDS Vigil being held at MCC San Diego, CA. I heard a song, "For Those Tears I Died", and I asked Jesus to come into my life and my heart. And He did.

My life changed and I began to live a Christian life once again, only differently. I just praised Jesus for the peace that I had found in my life. I got sicker and ended up in a wheelchair. I became depressed again and started to doubt Jesus. Oh no, the same scenario.

I met Rev. Larry Whitsell. I didn't like him at first but then I got sicked and I asked Rev. Whitsell to pray for me and that started our friendship. God spoke to me through Rev. Whitsell and I started to see Jesus in a different light; a light that I had been blinded to by my past religious beliefs.

I started telling people my story and touching many. I began to sing again. I was doing good and I started praying to God, "What am I to do with my life that is Your will?" And God answered, "To reach out to those who have been affected by the AIDS epidemic and let them know that I love them."

That ministry became a reality in February 1988. God has blessed that ministry over and over and many people come from many different walks of life and religions to volunteer their time in helping people.

I went to a healing service in Houston, Texas where Rev. Elder Jeri Ann Harvey was speaking and telling of God's wonderful healing presence. I went forward at altar call and she laid those wonderful healing hands on me. I was slain in the Spirit and spoke in tongues. I was one who didn't believe in this. Boy, did she ever wake me up to the Holy Spirit. All this took place in January 1990. In March 1990, I removed my wheelchair and walker from my home; I was healed and could walk again. My Doctors were even surprised; they were fitting me for braces on my legs at the time of this healing.

I have gone on to accomplish many things: Diablo Valley MCC (DVMCC) Board of Directors, Founder of the DVMCC Sunday School program, graduating from college with a triple major, and starting Samaritan College to become a licensed Clergy within UFMCC.

God has given me so much and AIDS has been a blessing in my life. So many memories to remember and cherish. I just celebrated 4 years of LIVING WITH AIDS. Praise God!!

Thank you Rev. Harvey for showing me the Holy Spirit and the unconditional healing powers of Jesus Christ.

I thank God daily for Rev. Whitsell, Jim Arlt, and my mom and day, my sister Rosie, my grandma, and my aunt for all the love and support that they have given on an unconditional level.

I thank God for my church family, Diablo Valley MCC, for helping me grow in the Spirit of Christ and for helping me learn how to live a Christian life.

I thank God for my spouse, Scott, who God brought into my life 5 months ago. God has blessed us with love and care for one another. God has shown me that love never dies and no matter the cause, love is abounding through Jesus. Scott and I met at District Conference in Sacramento, CA in May 1990. Thanks Scooter for being by my side these past few months.

Most importantly, I thank God for all that God has given me and for all the life that I have been allowed to live.

I hope that this touches at least one person and they can find the reason to live life to its fullest. And for the "healthy" ones out there, life is precious and we should never take it for granted that we have tomorrow.

I write this with all the love in my heart for you.

- - - - - - - - - - -

To Subscribe to ALERT please write to the UFMCC AIDS Ministry, 5300 Santa Monica Blvd., Suite 304, Los Angeles, CA 90029, and we will send you a sample copy of ALERT and a form for you to fill out. ATTENTION: PWA's/PWARC's and any group or organization who is a service provider for AIDS will receive ALERT free of charge. (Enclosed for your convenience is an offering envelope for the UFMCC AIDS Ministry. Thank you for your support!)